EXHIBIT D

JC821 U.S. PTO 10/425908 04/29/03

037633B

DEC 14 2004

PATENT NUMBER and ISSUE DATE 6830051

6830051

U.S. UTILITY Patent Application

APPL NUM	FILING DATE	CLASS	SUBCLASS	GAU	EXAMINER
10425908	04/29/2003	~~433~~ 128	80	~~3732~~ 3764	

**APPLICANTS: Frank Lesniak; Michael Lesser;

**CONTINUING DATA VERIFIED: None MB

** FOREIGN APPLICATIONS VERIFIED: None MB

PG-PUB	DO NOT PUBLISH ☒	RESCIND ☐	
Foreign priority claimed	☐ yes ☑ no		ATTORNEY DOCKET NO
35 USC 119 conditions met	☐ yes ☐ no		02-4060
Verified and Acknowledged Examiner's Initials	MB		

TITLE : Interocclusal appliance

U.S.DEPT. OF COMM./PAT.& TM-PTO-436L(Rev. 12-94)

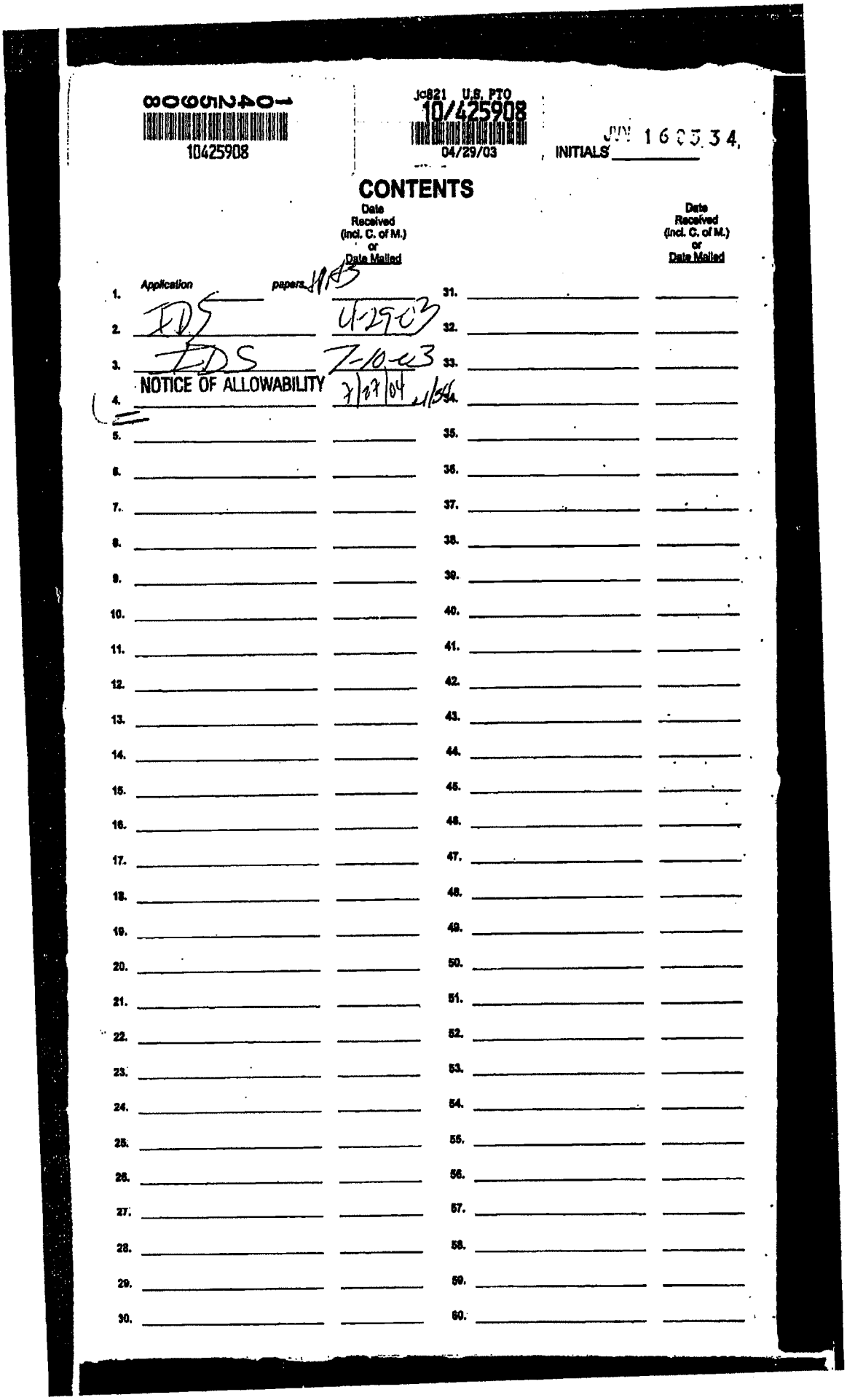
11/5/04 3 1 4/29/03

NOTICE OF ALLOWANCE MAILED		CLAIMS ALLOWED	
7/27/04	Assistant Examiner	Total Claims 17	Print Claim for O.G 1
ISSUE FEE		DRAWING	
Amount Due $665.00 / Date Paid 8/30/04 JM	MICHAEL A. BROWN PRIMARY EXAMINER	Sheets Drwg. 4	Figs.Drwg. 7 / Print Fig. 1
☐ TERMINAL DISCLAMER	Primary Examiner Michael A. Brown	Application Examiner D. Bryce	7/30/04
	PREPARED FOR ISSUE		

WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 368, Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only.

FILED WITH: ☐ DISK (CRF) ☐ CD-ROM

(Attached in pocket on right inside flap)



80652401
10425908

jc821 U.S. PTO
10/425908
04/29/03

JUN 16 03 34
INITIALS

CONTENTS

		Date Received (Incl. C. of M.) or Date Mailed			Date Received (Incl. C. of M.) or Date Mailed
1.	Application papers	MAS	31.		
2.	IDS	4-29-03	32.		
3.	IDS	7-10-03	33.		
4.	NOTICE OF ALLOWABILITY	7/27/04	34.		
5.			35.		
6.			36.		
7.			37.		
8.			38.		
9.			39.		
10.			40.		
11.			41.		
12.			42.		
13.			43.		
14.			44.		
15.			45.		
16.			46.		
17.			47.		
18.			48.		
19.			49.		
20.			50.		
21.			51.		
22.			52.		
23.			53.		
24.			54.		
25.			55.		
26.			56.		
27.			57.		
28.			58.		
29.			59.		
30.			60.		

ISSUE SLIP STAPLE AREA (for additional cross-references)

ISSUING CLASSIFICATION									
ORIGINAL		CROSS REFERENCE(S)							
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)						
128	859	128	861	862					
INTERNATIONAL CLASSIFICATION									
A61C	5/14								
	/								
	/								
	/								
	/		^ Continued on Issue Slip Inside File Jacket						

INDEX OF CLAIMS

✓ ..... Rejected – (Through numeral) ... Canceled N ..... Non-elected A ..... Appeal
= ..... Allowed + ... Restricted I ..... Interference O ..... Objected

Claim Final	Claim Original	Date
1	1	4/22/08
2	2	
3	3	
4	4	
5	5	
6	6	
7	7	
8	8	
9	9	
10	10	
11	11	
12	12	
13	13	
14	14	
15	15	
16	16	
17	17	
	18	
	19	
	20	
	21	
	22	
	23	
	24	
	25	
	26	
	27	
	28	
	29	
	30	
	31	
	32	
	33	
	34	
	35	
	36	
	37	
	38	
	39	
	40	
	41	
	42	
	43	
	44	
	45	
	46	
	47	
	48	
	49	
	50	

Claim Final	Claim Original	Date
	51	
	52	
	53	
	54	
	55	
	56	
	57	
	58	
	59	
	60	
	61	
	62	
	63	
	64	
	65	
	66	
	67	
	68	
	69	
	70	
	71	
	72	
	73	
	74	
	75	
	76	
	77	
	78	
	79	
	80	
	81	
	82	
	83	
	84	
	85	
	86	
	87	
	88	
	89	
	90	
	91	
	92	
	93	
	94	
	95	
	96	
	97	
	98	
	99	
	100	

Claim Final	Claim Original	Date
	101	
	102	
	103	
	104	
	105	
	106	
	107	
	108	
	109	
	110	
	111	
	112	
	113	
	114	
	115	
	116	
	117	
	118	
	119	
	120	
	121	
	122	
	123	
	124	
	125	
	126	
	127	
	128	
	129	
	130	
	131	
	132	
	133	
	134	
	135	
	136	
	137	
	138	
	139	
	140	
	141	
	142	
	143	
	144	
	145	
	146	
	147	
	148	
	149	
	150	

If more than 150 claims or 9 actions staple additional sheet here

SEARCH

Class	Sub.	Date	Exmr.
128	846 848 859 V 862	4/21/04	MB
602	902		
433	6		

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
128	846 848 859 V 862	4/21/04	MB
602	902		
433	6		

SEARCH NOTES

(List databases searched. Attach search strategy inside.)

	Date	Exmr.

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

07/01/2003 HMARZII 00000042 10425908
01 FC:2001 375.00 OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-267/69033

04/29/03 JC860 U.S. PTO

04-30-03 10/425908 .042903

PTO/SB/05 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Please type a plus sign (+) inside this box → ⊞
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	02-4060
First Inventor	LESNIAK
Title	INTEROCCLUSAL APPLIANCE
Express Mail Label No.	EV078024353US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification [Total Pages 28] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 3]
5. Oath or Declaration [Total Pages 2]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 18 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76
7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

ACCOMPANYING APPLICATION PARTS

9. [X] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [X] Power of Attorney (2)
11. [ ] English Translation Document *(if applicable)*
12. [X] Information Disclosure Statement (IDS)/PTO-1449 [X] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [X] Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent. (2)
17. [ ] Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: _____ / _____

Prior application information: Examiner _____ Group Art Unit: _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

[X] Customer Number or Bar Code Label [redacted] or [ ] Correspondence address below

Name	28143 PATENT TRADEMARK OFFICE				
Address					
City		State		Zip Code	
Country		Telephone		Fax	

Name (Print/Type)	SETH NATTER	Registration No. (Attorney/Agent)	25,122
Signature	[signature]	Date	04/29/2003

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

JC821 U.S. PTO 10/425908 04/29/03

6

10425908 .042903

PTO/SB/17 (01-03)
Approved for use through 04/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

[X] Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 415

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	LESNIAK
Examiner Name	
Art Unit	
Attorney Docket No.	02-4060

METHOD OF PAYMENT (check all that apply)

[ ] Check [X] Credit card [ ] Money Order [ ] Other [ ] None

[X] Deposit Account:

Deposit Account Number: 14-0470

Deposit Account Name: NATTER & NATTER

The Commissioner is authorized to: (check all that apply)

[ ] Charge fee(s) indicated below [X] Credit any overpayments

[ ] Charge any additional fee(s) during the pendency of this application

[ ] Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	375
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 375

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims	20	-20** = 0	X	= 0
Independent Claims	3	-3** = 0	X	= 0
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	40
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 40

SUBMITTED BY

(Complete if applicable)

Name (Print/Type)	SETH NATTER	Registration No. (Attorney/Agent)	25,122	Telephone	212-840-8300
Signature				Date	04/29/2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

10425908.042903

PTO/SB/35 (11-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)

First Named Inventor	LESNIAK
Title	INTEROCCLUSAL APPLIANCE
Atty Docket Number	02-4060

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

April ~~March~~ 23, 2003
Date

Frank B. Lesniak
Signature

FRANK LESNIAK
Typed or printed name

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

Burden Hour Statement: This collection of information is required by 37 CFR 1.213(a). The information is used by the public to request that an application not be published under 35 U.S.C. 122(b) (and the PTO to process that request). Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This form is estimated to take 6 minutes to complete. This time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

8

10425908 .042903

PTO/SB/35 (11-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)	First Named Inventor	LESNIAK
	Title	INTEROCCLUSAL APPLIANCE
	Atty Docket Number	02-4060

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

April 28
~~March~~ , 2003
Date

Signature

MICHAEL S. LESSER
Typed or printed name

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

425,908

Abstract of the Disclosure

An interocclusal appliance includes a maxillary impression preform of a resilient thermoplastic having a low softening temperature, e.g. 36°C, such as an EVA copolymer having approximately thirty percent vinyl acetate. The preform is molded over and unitarily bonded to a base having a planar bottom face contacted by mandibular occlusal surfaces. The base is formed of a thermoplastic having a higher softening temperature, e.g. 70°C, with the bond between the preform and base characterized by high shear strength. The preform includes a bight shaped centric relation positioning channel having a thick footing and draft along lingual, buccal and labial walls. The appliance is fitted by immersion in hot water to soften the preform, seating the maxillary arch within the channel and biting, such that the impression of the maxillary dentition embeds in the softened preform. Upon cooling, the preform is transformed into a reusable resilient encasement for the maxillary dentition. Suitable thermoplastics for implementation as the base include an EMA copolymer, blends of EMA and EVA or TPU or blends of TPU and EVA.

INTEROCCLUSAL APPLIANCE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to the subconscious parafunctional mandibular habits known as bruxism or clenching and more particularly an interocclusal appliance for the prevention of tooth structure loss resulting therefrom.

2. Antecedents of the Invention

Various studies have been undertaken with respect to the causative factors and precise mechanisms involved in bruxism and clenching. For example, it has been found and that bruxing events could be categorized based on mandibular position patterns.

Studies have also demonstrated that the highest amplitude of nocturnal bite force during bruxism could exceed the amplitude of the maximum voluntary bite force during the daytime. Bruxism and clenching have been found to constitute a major factor in conjunction with occlusal surface wear and constitute a significant potential risk factor for implant failure.

Interocclusal appliances, such as nightguards, have been long recognized as beneficial for the alleviation of the adverse effects of bruxism and clenching.

Prior interocclusal appliances included those fitted by a dental professional and those which were self fitted. Professionally fitted interocclusal appliances were molded of

11

relatively hard acrylic resin from casts of the patient's mouth taken from a dental impression. This procedure was both time consuming and expensive.

A typical self fitted interocclusal appliance included a thermoplastic channel trough in the configuration of a maxillary arch. Carried in the trough was a thermoplastic impressionable liner material having a softening point temperature lower than that of the trough. The liner was molded to conform to the mouth of the user after the appliance was immersed in hot water and then inserted into the mouth, with the liner placed against the maxillary arch. The user's jaw was then closed and biting pressure was applied to force the maxillary teeth into the liner.

Problems which were encountered with respect to self fitting nightguards included those related to the fitting procedure itself and to the durability of the appliance. The inability to properly center and align, i.e. register, the heated impressionable liner material of the nightguard relative to one's own maxillary arch constituted a major deficiency. When the nightguard was not properly registered, an improper fit was obtained, resulting in discomfort as well as premature appliance wear.

Further problems were encountered with respect to the structural integrity of self fitting nightguards. As a result of the shear forces which were generated during bruxing or clenching events, separation of the bond between the liner and the trough occurred. With the trough in contact with the mandibular occlusal surfaces and

the maxillary teeth embedded in the liner, lateral, superior and anterior mandibular deviations during bruxing events resulted in shear stress which separated the liner from the trough, rendering the appliance unserviceable.

SUMMARY OF THE INVENTION

A self fitting interocclusal appliance includes a base having a generally planar, smooth, occlusal face and a pair of parallel curved side walls. The base is molded of a thermoplastic having a Vicat softening temperature of at least 65°C and a Shore A hardness of at least 80.

Molded into the base between and above the side walls is an impression preform comprising an EVA copolymer having approximately thirty percent vinyl acetate, a Vicat softening temperature of approximately 36°C and a Shore A hardness below 80.

The preform includes a thick footing having a planar upper face and a shallow bight shaped centric relation pilot channel defined by peripheral walls which are sloped downwardly and inwardly from an elevation above the side walls of the base. The upper face of the footing defines the bottom of the pilot channel.

The base and preform are bonded to form a unitary appliance which is fitted by immersion in hot water such that the preform copolymer reaches a temperature above its softening temperature yet which can be comfortably withstood by oral tissue. The appliance is thereafter inserted in the oral cavity with the centric relation pilot channel substantially registered with the teeth

of the maxillary arch. Light pressure is applied to seat the maxillary occlusal surfaces in the shallow preform pilot channel, after which biting pressure is applied to imbed the maxillary teeth in the preform footing.

Since the softening temperature of the base thermoplastic was not attained during the heating step, significant deformation of the base is avoided and the upper and lower occlusal surfaces are separated by at least the thickness of the base.

Upon cooling to oral cavity temperature, the preform is transformed into a reusable resilient flexible encasement for the maxillary dentition (maxillary encasement), with the appliance to be removed during day time hours and reused at bed time.

Suitable thermoplastics for employment as the preform include ELVAX® EVA copolymer and suitable thermoplastics for employment as the base include ELVALOY® EMA copolymer, ELVALOY® EMA blended with ELVAX® EVA or ELVALOY® EMA blended with PELLETHANE® TPU elastomer.

From the foregoing compendium, it will be appreciated that it is an aspect of the present invention to provide an interocclusal appliance of the general character described which is not subject to the disadvantages of the antecedents of the invention aforementioned.

A feature of the present invention is to provide an interocclusal appliance of the general character described which is particularly well adapted for self fitting.

It is a consideration of the present invention to provide an interocclusal appliance of the general character described which is well-suited for economical mass production fabrication.

Another aspect of the present invention is to provide an interocclusal appliance of the general character described which is configured for accurate centric relation self fitting.

A further feature of the present invention is to provide an interocclusal appliance of the general character described which reduces stresses imposed on tooth surfaces during bruxing events.

Another consideration of the present invention is to provide an interocclusal appliance of the general character described which is safe and easy to use.

Yet another aspect of the present invention is to provide an interocclusal appliance of the general character described suited for extended usage without deterioration.

To provide an interocclusal appliance of the general character described having a base and an impression material unitarily molded thereto and characterized by a high shear resistance bond between components is a still further consideration of the present invention.

Another feature of the present invention is to provide an interocclusal appliance of the general character described which prevents loss of tooth structure otherwise resulting from bruxing events.

Another aspect of the present invention is to provide an interocclusal appliance of the general character described which is uninhibiting and comfortable to wear.

To provide an interocclusal appliance of the general character described which reduces compressive and lateral forces upon individual tooth surfaces occurring during bruxing events is a still further consideration of the present invention.

A further feature of the present invention is to provide an interocclusal appliance of the general character described which promotes restful sleep.

Further aspects, features and considerations of the present invention in part will be obvious and in part will be pointed out hereinafter.

With these ends in view, the invention finds embodiment in the various combinations of elements, arrangements of parts and series of steps by which the aforesaid aspects, features and considerations and certain other aspects, features and considerations are attained, all with reference to the accompanying drawings and the scope of which will be more particularly pointed out and indicated in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings in which is shown some of the various exemplary embodiments of the invention,

FIG. 1 is a perspective illustration of an interocclusal appliance constructed in accordance with and embodying the invention showing an impression preform having a shallow pilot channel molded over a base,

FIG. 2 is a top plan view of the interocclusal appliance, illustrating the impression preform,

FIG. 3 is a bottom view of the appliance, showing a smooth occlusal face of the base,

FIG. 4 is a front elevational view of the interocclusal appliance, illustrating a labial face of the base and a buccal peripheral wall of the impression preform,

FIG. 5 is a rear elevational view of the interocclusal appliance, illustrating a tapered lingual side wall of the base,

FIG. 6 is a sectional view through the interocclusal appliance, the same being taken substantially along the line 6--6 of FIG. 5, and

FIG. 7 is a side elevational view of the appliance, showing a downwardly, forwardly sloped buccal side wall of the base and a buccal peripheral wall of the preform.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in detail to the drawings, the reference numeral 10 denotes generally an interocclusal appliance constructed in accordance with and embodying the invention. The appliance 10 includes a lower base 12 having a plan configuration in the general shape of a maxillary dental arch. Molded to the base 12 is an impression preform 14. The impression preform 14 is transformed into a maxillary dentition encasement during self-fitting of the interocclusal appliance 10.

The base 12 is substantially of uniform thickness throughout, e.g. 2 mm, and includes a generally planar occlusal face 16, an upwardly outwardly tapered lingual side wall 18 and a buccal side wall 20. The buccal side wall 20 slopes downwardly from the rear of the appliance toward its labial face 22 as shown in FIG. 7.

Pursuant to the invention, the impression preform 14 includes a shallow, e.g. between 2 and 2½ mm deep, bight shaped centric relation pilot channel 24 configured to facilitate emplacement of the teeth of the user's maxillary arch at optimal position during and throughout self fitting of the appliance. The pilot channel includes a planar face 25. A footing having a height 26 extends from a horizontal upper surface of the base 12 to the channel face 25.

The shallow pilot channel 24 is defined by the face 25 and a pair of upwardly extending peripheral walls, i.e. a lingual peripheral wall 28, having an upper ridge 29, and a buccal peripheral wall 30, having an upper ridge 31. The buccal peripheral wall 30

includes a labial notch 32. The height of the buccal peripheral wall 30 above the face 25 is approximately between 2 and 2½ mm and is substantially uniform throughout (except at the notch 32). The height of the lingual peripheral wall is approximately 2 mm at the rear of the pilot channel and approximately 1 mm at a middle reduced height section 35.

It should be noted that the exterior surfaces of the lingual channel peripheral wall 28 and the buccal channel peripheral wall 30 are upwardly inwardly sloped from the top edge of the base side walls 18, 20. Similarly, an inner face 34 of the channel peripheral wall 28 and an inner face 36 of the channel peripheral wall 30 taper or slope at a draft angle from their respective ridges 29, 31, to the face 25 to facilitate self placement and registration of the maxillary teeth in the shallow pilot channel 24. The width of the channel face between the peripheral walls 28, 30 is approximately 9 mm. at the ends of the channel and approximately 6 mm. at its center. It should be understood that the dimensions herein are merely exemplary and differently sized appliances are appropriate, depending upon the dimensions of the user's dentition.

It should also be noted that the lingual side wall 18 of the base tapers downwardly, toward the front of the appliance, where it meets the upper surface of the base, as can be more readily seen in FIG. 5 and FIG. 6.

The upper surface of the base and the opposed inner surfaces of the side walls 18, 20, all of which are bonded to the impression preform 14 when the preform is molded over the base, is designated by the reference numeral 38 in FIG. 5.

The height 26 of the preform footing varies from a maximum height, shown in FIG. 5 at the rear of the appliance, e.g. 6 to 6½ mm to a minimum height of approximately 4 mm at the front center of the appliance as shown in FIG. 6. The preform footing constitutes the primary source of impressionable material which forms around and conforms to the shape of the maxillary dentition during self-fitting.

It is significant that the thermoplastic material selected for the base has a softening temperature sufficiently above that of the impression preform material such that the thickness of the base is not significantly reduced as a result of the compressive forces applied during fitting.

Rheological characteristics of the base thermoplastic include a Vicat softening temperature (ASTM D1525) of at least 65°C, which is well above the temperatures reached during the fitting procedure, e.g. 40°C to 46°C.

The mold bond between the base and the impression preform 14 (which is transformed into the maxillary encasement) is required to withstand the lateral and compressive stresses encountered during bruxing or clenching events at oral cavity temperatures.

In accordance with the present invention, the base 12 is formed by injection molding a thermoplastic resin having requisite characteristics into a base mold cavity. The molded base 12 is positioned in an occlusal appliance mold cavity and a thermoplastic resin having the requisite characteristics for the impression preform 14 is injected into the appliance mold cavity over the base 12 and unitarily bonds thereto.

Suitable resins for employment as the impression preform include an ethylene vinyl acetate (EVA) copolymer available from the Du Pont under the trademark ELVAX® having a vinyl acetate content of at least 25%. A preferred EVA copolymer is ELVAX®150 having a 33% vinyl acetate content by weight, a Vicat softening temperature of 36°C and a Shore A hardness of 73.

Preferred embodiments of the invention may be fabricated in accordance with the following examples:

EXAMPLE No. 1

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY®1609 AC EMA	100%

The ELVALOY®1609 AC ethylene methyl acrylate copolymer (available from DuPont) was heated to a recommended molding temperature and injection molded into the base mold cavity. The ELVALOY®1609 AC EMA copolymer contains approximately 9% by weight acrylate and exhibits a Vicat softening temperature of 70°C and a Shore A hardness of 97.

The following thermoplastic resin was utilized as the impression preform material:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA copolymer	100%

The ELVAX®150 EVA was heated to a recommended molding temperature above its melting point and injection molded into an occlusal appliance mold cavity over the molded base positioned within the mold cavity. The unitary interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and the molded over impression preform, both before and after fitting.

The interocclusal appliance of EXAMPLE No. 1 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

It was noted that due to the compressive forces applied during the fitting procedure, slight base deformation occurred in the nature of minor indentations in the occlusal face 16, however, the base thickness was not compromised, such that a minimum spacing between occlusal surfaces of at least the thickness of the base, e.g. 2mm, resulted.

EXAMPLE No. 2

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
PELLETHANE® 2103 - 80 AEN TPU elastomer	50%
ELVAX®750 EVA	50%

ELVAX®750 EVA comprises an ethylene vinyl acetate copolymer available from DuPont and having a 9% vinyl acetate content by weight and PELLETHANE®2103 - 80 AEN comprises a thermoplastic polyurethane elastomer available from Dow Chemical Co.

Equal amounts by weight of PELLETHANE®2103 - 80 AEN and ELVAX®750 were blended by conventional apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity.

The molded base 12 was positioned in an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA	100%

The ELVAX®150 EVA was heated to a recommended molding temperature

above its melting point and injection molded into the occlusal appliance mold cavity over the molded base.

The interocclusal appliance was removed from the mold cavity and exhibited a high adhesion bond between the base and the impression preform before and after fitting.

The interocclusal appliance of EXAMPLE No. 2 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Greater base deformation occurred during fitting than in Example 1, however, the base thickness was not compromised and a minimum spacing between occlusal surfaces of at least the thickness of the base, e.g. 2mm. was maintained.

EXAMPLE No. 3

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY®1609 AC EMA	90%
ELVAX®750 EVA	10%

Ninety percent (90%) by weight of ELVALOY®1609 AC EMA was blended with ten percent (10%) by weight ELVAX®750 EVA with conventional blending apparatus. The blend was then heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 90.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA	100%

The ELVAX®150 EVA was heated to a recommended molding temperature above its melting point and injection molded into the occlusal appliance mold cavity over the molded base.

The interocclusal appliance was removed from the mold cavity and exhibited a high adhesion bond between the base and the impression preform both before and after fitting.

The interocclusal appliance of EXAMPLE No. 3 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The

appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, somewhat greater than that of the base in EXAMPLE No. 1, however, less than the base deformation which occurred in EXAMPLE No. 2.

EXAMPLE No. 4

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY®1609 AC EMA	75%
ELVAX®750 EVA	25%

Seventy five percent (75%) ELVALOY®1609 AC EMA by weight is blended with 25% by weight ELVAX®750 EVA, utilizing conventional mixing apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 92.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and the molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 4 was heated by immersion in boiling water for approximately 40 seconds, removal from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, e.g. approximately the same as occurred with respect to EXAMPLE No. 2. The base thickness was not compromised, however, and a minimum spacing between occlusal services of at least the thickness of the base was maintained.

EXAMPLE No. 5

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY®1609 AC EMA	50%
ELVAX®750 EVA	50%

Fifty percent (50%) ELVALOY®1609 AC EMA by weight was blended with fifty percent (50%) by weight ELVAX®750 EVA, utilizing conventional mixing apparatus. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. The molded base 12 exhibited a Shore A hardness of 95.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the

mold cavity exhibited a high adhesion bond between the base and molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 5 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Some deformation of the base occurred during fitting, i.e. greater than the deformation which occurred with respect to EXAMPLE No. 2. The base thickness was not compromised, however, and a minimum spacing between occlusal surfaces of at least the thickness of the base was maintained.

EXAMPLE No. 6

A base 12 was injection molded utilizing the following resin formulation:

BASE RESIN	PERCENTAGE BY WEIGHT
ELVALOY®1609 AC EMA	90%
PELLETHANE®2103-80 AEN TPU	10%

Ninety percent (90%) ELVALOY®1609 AC by weight is blended with ten percent (10%) PELLETHANE®2103-80 AEN. The blend was heated to a suitable molding temperature and thereafter injection molded into the base mold cavity. Molded base 12 exhibited a Shore A hardness of 95.

The molded base 12 was then inserted into an occlusal appliance mold cavity and the following thermoplastic resin was utilized as the impression preform:

PREFORM RESIN	PERCENTAGE BY WEIGHT
ELVAX®150 EVA	100%

The ELVAX®150 EVA preform resin was heated to a suitable molding temperature and injection molded into an occlusal mold appliance cavity after the molded base had been positioned in the cavity. The interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and molded over impression preform, both before and after the fitting.

The interocclusal appliance of EXAMPLE No. 6 was heated by immersion in boiling water for approximately 40 seconds, removed from the boiling water and immersed in water at or below room temperature for approximately 1 second. The appliance was then inserted into the oral cavity, with the maxillary occlusal surfaces seated in the shallow centric relation pilot channel.

Thereafter, biting pressure was applied and the maxillary teeth were impressed into the impression preform. The impression preform material flowed over, around and conformed to the shape of the surfaces of the maxillary dentition. Upon cooling, the impression preform was transformed into a reusable flexible maxillary encasement.

Slight base deformation occurred during fitting, i.e. less than the deformation which occurred with respect to EXAMPLE No. 1.

Other suitable base resin formulations comprise blends of ELVALOY ® 1609 AC EMA and PELLETHANE ® 2103-80 AEN TPU ranging between 10% to 50% TPU by weight. Additional base resin formulations may comprise linear low density polyethylene (LLDPE), low density polyethylene (LDPE) or blends of ELVAX 750 EVA and LLDPE or LDPE with the LLDPE or LDPE content ranging from 25% to 90% by weight.

It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention. The principal rheological and other attributes of the selected resins include a suitable softening temperature range for the impression preform resin which will not create temperature induced discomfort or damage to oral tissue, a softening temperature range and hardness of the base resin such that substantial deformation of the base does not occur during fitting and over prolonged usage.

An additional and significant characteristic upon which the selection of resins is predicated is the ability to obtain a unitary molded over bond between the base and the preform/maxillary dentition encasement which is well-suited to withstand the high shear and compression forces generated during bruxing and clenching events.

In this regard, it should be noted that in the foregoing examples, the surface 38 of the base over which the impression preform resin is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention.

Also within the purview of the invention is the utilization of the interocclusal appliance in an inverted state, that is having the occlusal face 16 of the base in contact with maxillary occlusal surfaces and the mandibular dentition impressed in the impression preform.

Thus it will be seen that there is provided an interocclusal appliance which achieves the various aspects, features and considerations of the present invention and which is well-suited to meet the conditions of practical usage.

Since various possible embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments shown herein,

without departing from the spirit of the invention, it should be understood that all matter herein described or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense.

Having thus described the invention there is claimed as new and desired to be secured by Letters Patent:

1. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the appliance comprising a base and an impression preform unitarily bonded thereto, the base having a plan configuration of a dental arch and a generally planar occlusal face, the impression preform being bonded to an opposite face of the base, the impression preform including a bight shaped shallow centric relation pilot channel, the pilot channel having a generally planar face and a pair of spaced peripheral walls, the impression preform further including a footing having a height extending from the opposite face of the base to the face of the pilot channel, the impression preform comprising a resin having a Shore A hardness below 80 and a Vicat softening temperature, the base comprising a resin having a hardness of at least Shore A 80 and a Vicat softening temperature above that of the impression preform resin.

2. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the impression preform resin comprises an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

3. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 2 wherein the base resin comprises an ethylene methyl acrylate copolymer.

4. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises an ethylene methyl acrylate copolymer.

5. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 4 wherein the ethylene methyl acrylate copolymer includes approximately 9% by weight acrylate.

6. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises a thermoplastic polyurethane elastomer blended with an ethylene vinyl acetate copolymer.

7. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the base resin comprises an ethylene methyl acrylate copolymer blended with a thermoplastic selected from the group consisting of ethylene vinyl acetate copolymer and thermoplastic polyurethane elastomer.

8. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the pilot channel has a depth in the order of 2 mm.

9. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein each peripheral wall includes a ridge and an inner face, the inner faces being sloped downwardly and inwardly from their respective ridges toward the face of the pilot channel.

10. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the face of the pilot channel is between approximately 6 mm to 9 mm wide.

11. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the height of the footing ranges from approximately 4 mm at the center of the pilot channel to at least 6½ mm at the rear of the pilot channel.

12. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 1 wherein the height of the footing is at least twice the distance between the occlusal face of the base and the opposite face of the base.

13. An interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the appliance comprising a base and an impression preform unitarily bonded thereto, the base having a plan configuration of a dental arch and a generally planar occlusal face, the impression preform being bonded to an opposite face of the base, the impression preform including a bight shaped shallow centric relation pilot channel, the pilot channel having a generally planar face and a pair of spaced peripheral walls, the impression preform further including a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base.

14. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the impression preform comprises an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate and the base comprises an ethylene methyl acrylate copolymer having approximately 9% by weight acrylate and a Vicat softening temperature of at least 70°C.

15. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the pilot channel has a depth which is approximately the distance between the occlusal face of the base and the opposite face of the base.

16. An interocclusal appliance for the alleviation of the adverse effects of bruxing or clenching events as constructed in accordance with claim 13 wherein the channel width is approximately 4 times the distance between the occlusal face of the base and the opposite face of the base.

17. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

a) molding and appliance base from a resin having a Vicat softening temperature of at least 70° C and a Shore A hardness of at least 80; and

b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

18. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events in accordance with claim 17 wherein the resin employed in step a) comprises an ethylene methyl acrylate copolymer having approximately 9% by weight acrylate.

19. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events in accordance with claim 17 wherein the resin employed in step a) comprises an ethylene methyl acrylate copolymer blended with a thermoplastic selected from the group consisting of ethylene vinyl acetate copolymer and thermoplastic polyurethane elastomer.

20. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events in accordance with claim 17 wherein the resin employed in step a) comprises a thermoplastic polyurethane elastomer blended with an ethylene vinyl acetate copolymer.

10425908 .042903

PTO/SB/01 (10-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☑ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	02-4060
First Named Inventor	LESNIAK
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

As the below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

INTEROCCLUSAL APPLIANCE

(Title of the invention)

the specification of which

☑ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) ☐ as United States Application Number or PCT International Application Number ☐ and was amended on (MM/DD/YYYY) ☐ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

38

10425908 . 042903

PTO/SB/01 (10-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ Customer Number or Bar Code Label	28143	OR ☐ Correspondence address below	
Name			
Address			
City		State	ZIP
Country	Telephone		Fax

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR : ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) FRANK		Family Name or Surname LESNIAK	
Inventor's Signature Frank M Lesniak			April 23, 2003 Date
Lansdale Residence: City	PA State	USA Country	USA Citizenship
Mailing Address c/o Hayloft Enterprises Inc. 1640 Wagon Wheel Lane			
Lansdale City	PA State	19446 ZIP	USA Country

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) MICHAEL S.		Family Name or Surname LESSER	
Inventor's Signature MS			April 28, 2003 Date
Green Brook Residence: City	NJ State	USA Country	USA Citizenship
Mailing Address c/o Dental Concepts LLC 650 From Road			
Paramus City	NJ State	07652 ZIP	USA Country

☐ Additional inventors are being named on the ___supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

[Page 2 of 2]

-30-

39

10425908.042903

Please type a plus sign (+) inside this box → [+]

PTO/SB/81 (02-01)
Approved for use through 10/31/2002. OMB 0651-0035
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	
First Named Inventor	LESNIAK
Title	INTEROCCLUSAL APPLIANCE
Group Art Unit	
Examiner Name	
Attorney Docket Number	02-4060

I hereby appoint:

[X] Practitioners at Customer Number 28143 → Label here 28143 PATENT TRADEMARK OFFICE

OR

[ ] Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

[ ] The above-mentioned Customer Number.

OR

[ ] Practitioners at Customer Number → *Place Customer Number Bar Code Label here*

OR

[ ] Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country					
Telephone		Fax			

I am the:

[X] Applicant/Inventor.

[ ] Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	FRANK LESNIAK
Signature	Frank Lesniak
Date	~~March~~ April 23, 2003

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[ ] *Total of _____ forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

40

10425908 .042903

Please type a plus sign (+) inside this box → [+]

PTO/SB/81 (02-01)
Approved for use through 10/31/2002. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	
First Named Inventor	LESNIAK
Title	INTEROCCLUSAL APPLIANCE
Group Art Unit	
Examiner Name	
Attorney Docket Number	02-4060

I hereby appoint:

[X] Practitioners at Customer Number 28143 →

OR

[ ] Practitioner(s) named below:

Label here 28143 PATENT TRADEMARK OFFICE

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

[ ] The above-mentioned Customer Number.

OR

[ ] Practitioners at Customer Number → *Place Customer Number Bar Code Label here*

OR

[ ] Firm or Individual Name					
Address					
Address					
City		State		Zip	
Country					
Telephone		Fax			

I am the:

[X] Applicant/Inventor.

[ ] Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	MICHAEL S. LESSER
Signature	
Date	~~March~~ April 28, 2003

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[ ] *Total of _____ forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

41

D&I
461

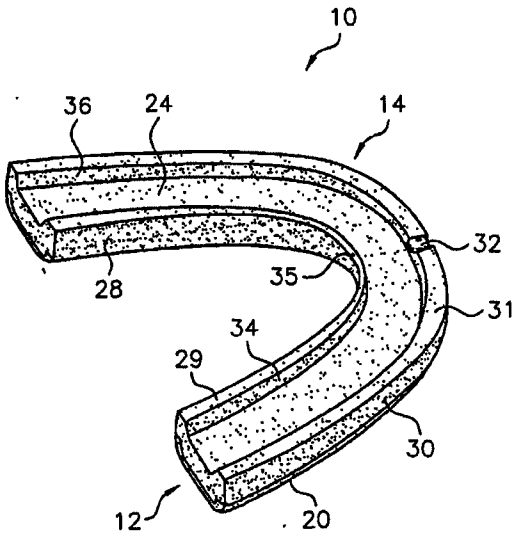


FIG. 1

PRINT OF DRAWINGS
AS ORIGINALLY FILE

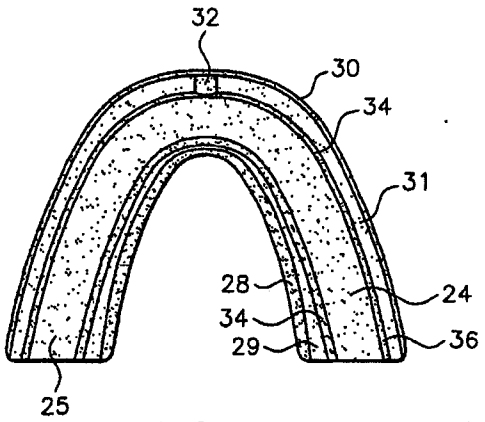


FIG. 2

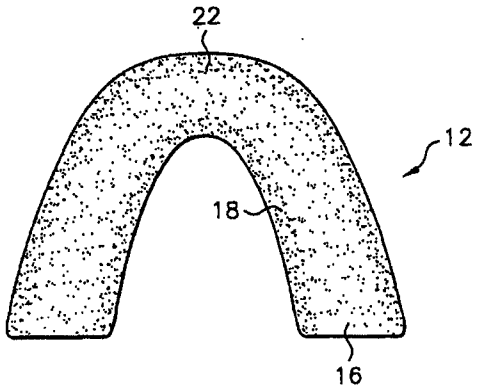


FIG. 3

PRINT OF DRAWINGS
AS ORIGINALLY FILE

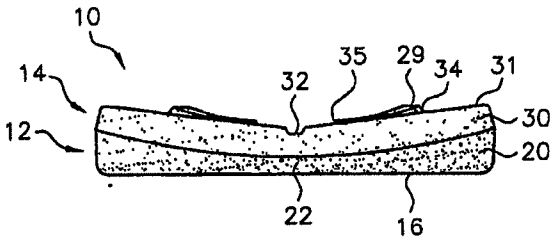


FIG. 4

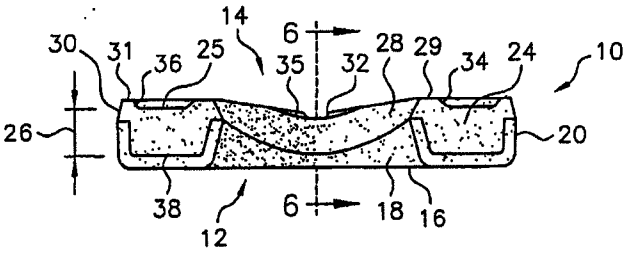


FIG. 5

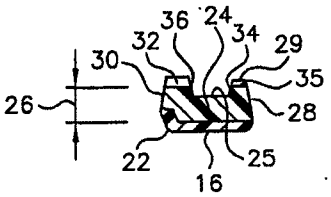


FIG. 6

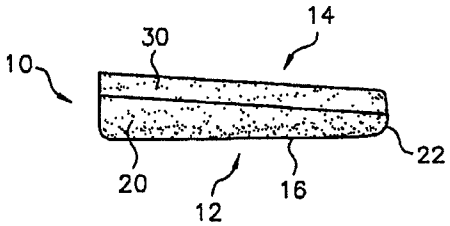


FIG. 7

6830051

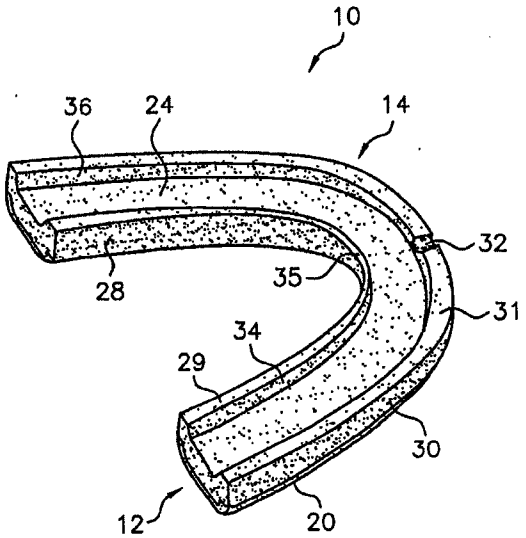


FIG. 1

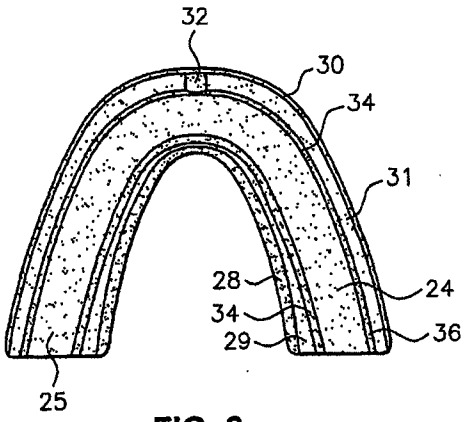


FIG. 2

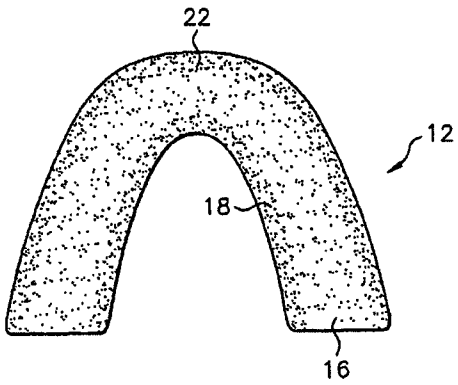


FIG. 3

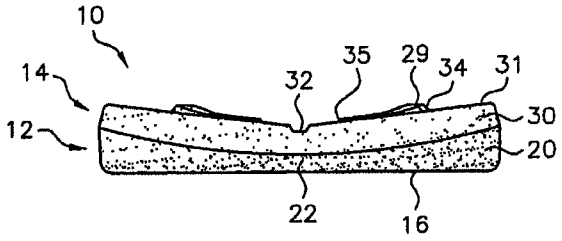


FIG. 4

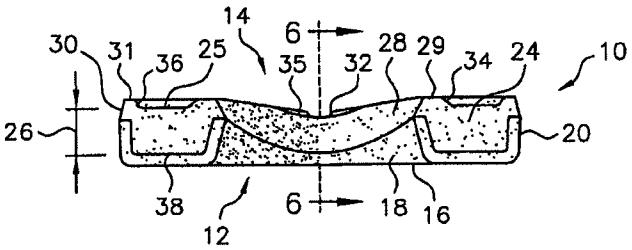


FIG. 5

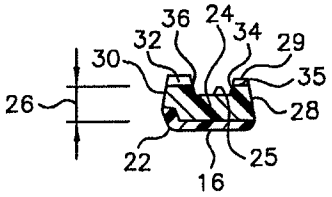


FIG. 6

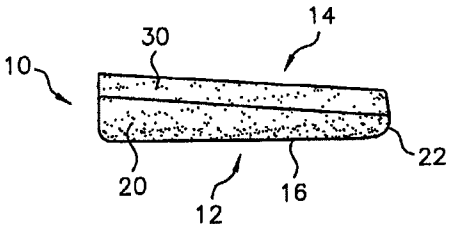


FIG. 7

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	LESNIAK
Art Unit	
Examiner Name	
Attorney Docket Number	02-4060-P

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MB		US-6,302,686	10-16-2001	CHOTT et al.	
		US-6,082,363	07-04-2000	WASHBURN	
		US-6,036,487	03-14-2000	WESTERMAN	
		US-5,746,221	05-05-1998	JONES et al.	
		US-5,646,216	07-08-1997	WATSON et al.	
		US-5,566,684	10-22-1996	WAGNER	
		US-5,406,963	04-18-1995	ADELL	
		US-5,339,832	08-23-1994	KITTELSEN et al.	
		US-5,328,362	07-12-1994	WATSON et al.	
		US-4,955,393	09-11-1990	ADELL	
		US-4,761,136	08-02-1988	MADHAVAN et al.	
		US-4,668,188	05-26-1987	WOLFENSON et al.	
		US-4,063,552	12-20-1977	GOING et al.	
		US-3,505,995	04-14-1970	GREENBERG	
		US-3,496,936	02-24-1970	GORES	
		US-3,247,844	04-26-1966	BERGHASH	
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	MB	Date Considered	4/22/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

OIPE JUL 10 2003 PATENT & TRADEMARK OFFICE 1600

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/425,908
Filing Date	4/29/2003
First Named Inventor	LESNIAK
Art Unit	3732
Examiner Name	
Attorney Docket Number	02-4060-P

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MB		US-6,302,686	10-16-2001	CHOTT et al.	
		US-6,082,363	07-04-2000	WASHBURN	
		US-6,036,487	03-14-2000	WESTERMAN	
		US-5,746,221	05-05-1998	JONES et al.	
		US-5,646,216	07-08-1997	WATSON et al.	
		US-5,566,684	10-22-1996	WAGNER	
		US-5,406,963	04-18-1995	ADELL	
		US-5,339,832	08-23-1994	KITTELSEN et al.	
		US-5,328,362	07-12-1994	WATSON et al.	
		US-4,955,393	09-11-1990	ADELL	
		US-4,761,136	08-02-1988	MADHAVAN et al.	
		US-4,668,188	05-26-1987	WOLFENSON et al.	
		US-4,063,552	12-20-1977	GOING et al.	
		US-3,505,995	04-14-1970	GREENBERG	
		US-3,496,936	02-24-1970	GORES	
		US-3,247,844	04-26-1966	BERGHASH	
		US-			
		US-			
		US-			
		US-			

RECEIVED
JUL 17 2003
TECHNOLOGY CENTER R3700

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	MB	Date Considered	4/22/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

3732

PTO/SB/21 (01-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/425,908
Filing Date	04/29/2003
First Named Inventor	LESNIAK
Art Unit	3732
Examiner Name	02-4060
Attorney Docket Number	

Total Number of Pages in This Submission

ENCLOSURES (Check all that apply)

- [ ] Fee Transmittal Form
- [ ] Fee Attached
- [ ] Amendment/Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [X] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Changes of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please identify below):
- [X] Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Seth Natter
Signature	
Date	July 8, 2003

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: July 8, 2003

Typed or printed	Seth Natter		
Signature		Date	July 8, 2003

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

28143 7590 07/27/2004

NATTER & NATTER
25 WEST 43 STREET
NEW YORK, NY 10036

EXAMINER	
BROWN, MICHAEL A	
ART UNIT	**PAPER NUMBER**
3764	4

DATE MAILED: 07/27/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/425,908	04/29/2003	Frank Lesniak	02-4060	5929

TITLE OF INVENTION: INTEROCCLUSAL APPLIANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	10/27/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 07/04) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

28143 7590 07/27/2004

NATTER & NATTER
25 WEST 43 STREET
NEW YORK, NY 10036

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/425,908	04/29/2003	Frank Lesniak	02-4060	5929

TITLE OF INVENTION: INTEROCCLUSAL APPLIANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	10/27/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
BROWN, MICHAEL A	3764	128-861000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:
- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):
- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is not claiming SMALL ENTITY status. See, e.g., 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

(Authorized Signature) (Date)

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

52

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/425,908	04/29/2003	Frank Lesniak	02-4060	5929

28143 7590 07/27/2004

NATTER & NATTER
25 WEST 43 STREET
NEW YORK, NY 10036

EXAMINER	
BROWN, MICHAEL A	

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 07/27/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 28 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 28 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 07/04) Approved for use through 04/30/2007.

53

Notice of Allowability

Application No.	Applicant(s)
10/425,908	Frank Kusnyk et al
Examiner	**Art Unit**
Michael Brown	3764

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to this application filed 4/29/03.
2. ☑ The allowed claim(s) is/are 1-17.
3. ☑ The drawings filed on 4/29/03 are acceptable as formal drawings.
4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____.
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   *Certified copies not received: _____.
5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION. This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. _____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.
8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☐ Notice of Informal Patent Application (PTO-152)
3. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
4. ☐ Interview Summary (PTO-413), Paper No. _____.
5. ☑ Information Disclosure Statement(s) (PTO-1449), Paper No(s). 2-3
6. ☐ Examiner's Amendment/Comment
7. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8. ☑ Examiner's Statement of Reasons for Allowance
9. ☐ Other

/Michael A. Brown/
MICHAEL A. BROWN
PRIMARY EXAMINER

REASON FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The prior art does not disclose or suggest in interocclusal appliance having a base that has a plan configuration of a dental arch and a generally planar occlusal face, impression material bonded to the base, the impression material has a pilot channel having a generally planar face and a pair of space peripheral walls, the impression material has a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 703-308-2682. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Brown
April 22, 2004

Michael A. Brown

MICHAEL A. BROWN
PRIMARY EXAMINER

Notice of References Cited

Application No.	Applicant(s)		
10/425,908	Frank Lesniak et al		
Examiner	Group Art Unit	Page 1 of 1	
Michael Brow	3764		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
X	A	4776792	10-1988	Wagner	433	71
X	B	5305741	4-1994	Mokes	128	207.14
X	C	5829441	11-1998	Kidd	128	858
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
X	N	0 359 135	3-1990	EP	Furumichi	—	—
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
	U		
	V		
	W		
	X		

* A copy of this reference is not being furnished with this Office action.
(See Manual of Patent Examining Procedure, Section 707.05(a).)

U.S. Patent and Trademark Office
PTO-892 (Rev. 9-96)

Part of Paper No. 4

*U.S. GPO: 1998-433-211/97502

AUG-23-2004 12:10 NATTER & NATTER 1212 302 0295 P.01/02

BEST AVAILABLE COPY

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

28143 7590 01/27/2004

NATTER & NATTER
25 WEST 43 STREET
NEW YORK, NY 10036

08/24/2004 TBESHAH2 00000013 10425908

01 FC:2501 665.00 OP

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

SETH NATTER (Depositor's name)
(Signature)
August 23, 2004 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/425,908	04/29/2003	Frank Lesniak	02-4060	5929

TITLE OF INVENTION: INTEROCCLUSAL APPLIANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	10/27/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
BROWN, MICHAEL A	3764	128-861000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 SETH NATTER
2 NATTER & NATTER
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: DENTAL CONCEPTS LLC
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Paramus, New Jersey

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):
☐ A check in the amount of the fee(s) is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is not claiming SMALL ENTITY status. See, e.g., 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

(Authorized Signature) (Date) 08/23/2004

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PAGE 1/2 * RCVD AT 8/23/2004 12:10:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/0 * DNIS:7464000 * CSID:1212 302 0295 * DURATION (mm-ss):01-04

58

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number: 10425908

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	26	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	26 minus 20=	* 6
INDEPENDENT CLAIMS	3 minus 3 =	* 0
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	375.00	OR	BASIC FEE	750.00
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 12/02) *U.S. Government Printing Office: 2003 — 498-278/59151 Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

59